

### **REMARKS**

Claims 1, 12, 13, 15-20, 24, 26-32, 34, 36-44, 47, 53, 67 and 73-80 are pending in the present application. Claims 1, 12, 13, 15-20, 24, 26-32, 34, 36-44, 47, 53, 67 and 75-80 stand rejected. Claims 1, 31, 47, 67 and 77 are amended herein. Applicants respectfully submit that no new matter has been added. Reconsideration of the application is respectfully requested.

**I. Claims 1, 12, 13, 15-20, 24, 26-32, 34, 36-44, 47, 53, 67 and 75-80, as amended, are Non-Obvious over to DeLaHuerga, alone or in combination.**

Claims 1, 12, 13, 15-20, 24, 26-32, 34, 36-44, 47, 53, 67 and 75-80 currently stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,408,330 to DeLaHuerga (hereinafter, "DeLaHuerga") in view of U.S. Patent No. 6,190,326 to McKinnon et al. (hereinafter, "McKinnon"). Claims 35-46 are rejected under 35 U.S.C. § 103(a) as being unpatentable over DeLaHuerga in view of Official Notice previously taken by the Examiner. Claims 16 and 19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over DeLaHuerga in view of McKinnon as applied to claim 1 and further in view of U.S. Patent No. 6,083,248 to Thompson (hereinafter, "Thompson"). These rejections are respectfully traversed, and withdrawal of the rejection is requested.

Claims 1, 31, 47, 67 and 77 are amended herein to better define the claimed subject matter. It is respectfully asserted that the claims are not rendered obvious by the art of record.

DeLaHuerga is related to an information gathering system where an information collections device (ICD) is used as a remote collection device. According to DeLaHuerga, the ICD is meant to be used with other "smart" devices such as an IV pump, medical container or patient identification bracelet. Each "smart" device consists of a processor, transceiver and memory. In each example, the physician causes the

processor to transmit the information segment to the ICD. Once the information segment is within the ICD, "In all cases the present invention contemplates that, prior to transmitting information packets to a browser, a physician must first log onto a computer via some procedure which identifies the physician and verifies that the physician is authorized to approve information units prior to permanent storage." (See column 12, lines 42-48).

McKinnon relates to a system that is capable of collecting and recording patient respiratory information for use in treatment of patients. The system includes both measurement functionality for the patient's condition and storage functionality. Measurements are made at the appropriate times and in accordance with the physician's instructions for later transmittal to the physician. The system is capable of communicating with one or more medication dispensing apparatuses for obtaining *confirmation* that an appropriate dosage of medication was actually administered. The system consists of a base unit including at least one processor that is programmed to perform the noted functions in conjunction with input/actions from the patient and at least one detachable mouthpiece unit for insertion into the base unit when a measurement is to be performed. When the mouthpiece unit is attached to the base unit, the sensors are able to deliver raw measurement data to the measurement functionality within the base unit for processing.

Applicants respectfully submit that DeLaHuerger and McKinnon do not render independent claims 1, 47, and 67, or the claims that depend therefrom obvious. Applicant's assert that the references relied upon, when taken as a whole, fail to include each element claimed in these independent claims, and as such, the examiner has failed to establish a prima facie case of obviousness under 35 USC 103. The Office has failed to provide any objective evidence of nonobviousness and DeLaHuerger and McKinnon, separately or combined, fail to disclose or support each element of Applicant's claims.

Claims 1, 47 and 67 call for transfer of data relevant to a patient's respiratory condition from a medicament delivery system to a network computer system and for the

medicament delivery system to be able to vary the dose of medicament deliverable thereby to the patient in response to data received from the network computer system.

In contrast to DeLaHuerga and McKinnon, Applicant's claimed invention is a system for delivery of a respirable medicament and the remote assessment of a patient's respiratory condition so that variation of the dose delivered by the system to the patient is possible. Both DeLaHuerga and McKinnon are related to data gathering (one-way data flow) and require steps subsequent to the data gathering to move the data to a processing node before any type of feedback can occur. The two-way transfer of data in Applicant's claimed system/method to allow variation of the medicament dose enables seamless remote assessment and prescription of medicament which is clearly unique to Applicant's claimed invention.

Neither DeLaHuerga or McKinnon teach a medicament delivery system which is arranged to vary the dose of medicament to be delivered, let alone in response to data received from a network computer system. Accordingly, DeLaHuerga and McKinnon, alone or in combination, do not disclose, teach, or suggest the system or method of claims 1, 47 and 67.

Claims 36-44 stand rejected based on DeLaHuerga in view of Official Notice taken by the Examiner. There is no support in any prior document for the assertion of Admitted Prior Art. In making this assertion, the Office has failed to provide in this Action supporting documentary evidence. If the Office is relying on common knowledge in the art, Applicant's request proof that the facts asserted are well known. The Office is reminded that, under MPEP Section 2144.03, it is never appropriate to rely solely on common knowledge in the art, without any evidentiary support in the record, as the principal evidence on which a rejection is based. Applicant's request that the Office provides supporting documentary evidence in this rejection or that this rejection be removed.

In addition, but without acquiescing to the rejection, claims 36-44 are in event allowable over DeLaHuerga and McKinnon by their dependency on claim 1.

Claims 16, and 19 stand rejected based on DeLaHuerga in view of McKinnon as applied to claim 1 above, and further in view of Thompson. It is noted that claims 16 and 19 depend from claim 1. For the reasons set forth above, applicants respectfully submit that DeLaHuerga in view of McKinnon fails to disclose, teach, or suggest each and every feature recited by claim 1. Thompson does not overcome the significant shortcomings of DeLaHuerga described above. Thompson discloses a system for communicating with a medical device implanted in an ambulatory patient and for locating the patient in order to selectively monitor device function, alter device operating parameters and modes and provide emergency assistance to and communications with a patient. DeLaHuerga and Thompson, alone or in combination, do not disclose, teach, or suggest a medicament delivery system that can be used to deliver medicament based on sensing breath. Thus, claims 16 and 19 are not rendered obvious by DeLaHuerga in view of McKinnon as applied to claim 1 above, and further in view of Thompson.

Therefore, for at least the reasons stated above, applicants respectfully submit that claims 11, 12, 13, 15-20, 24, 26-32, 34, 36-44, 47, 53, 67 and 75-80 are not rendered obvious by the cited references or official notice taken by the Examiner. Thus, applicants respectfully submit that the rejections of claims 1, 12, 13, 15-20, 24, 26-32, 34, 36-44, 47, 53, 67 and 75-80 under 35 U.S.C. § 103(a) should be withdrawn and the claims allowed at this time.

### **Conclusion**

All claim rejections being addressed in full, Applicant respectfully requests the withdrawal of the outstanding objections and rejections and the issuance of a Notice of Allowance.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge any fees or credit any overpayment, particularly including any fees required under 37 CFR §1.16 or §1.17, and any necessary extension of time fees, to Deposit Account No. 07-1392.

Should the Examiner have any questions regarding the foregoing, Applicant respectfully requests that the Examiner contact the undersigned, who can be reached at (919) 483-9995.

Respectfully submitted,

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